Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
July 19-20, 2023
Hybrid Virtual and In-Person Meeting

MEETING MINUTES

Note: *For details on this meeting, please refer to the transcript and slides posted here:* https://ncvhs.hhs.gov/meetings/full-committee-meeting-14/

The National Committee on Vital and Health Statistics (NCVHS) was convened both in person and virtually on July 19-20, 2023. The meeting was open to the public. Present:

Committee Members
Jacki Monson, JD, NCVHS Chair, Sutter Health
Angela Alton, MPA, City of Hope
Tammy Banks, MBA, FACMPE
Denise Chrysler, JD, Network for Public Health Law
Catherine Donald, MBA, Alabama Department of Public Health
James Ferguson, Kaiser Permanente
Melissa Goldstein, JD, GWU
Michael Hodgkins, MD, MPH
R. Lenel James, MBA, BCBSA
Richard Landen, MPH, MBA
Vickie Mays, PhD, MSPH, UCLA
Margaret Skurka, RHIA, CCS, FAHIMA, IU
Debra Strickland, MS, Conduent
Steve Wagner, MBA
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA, UPitt
Wu Xu, PhD, University of Utah

Executive Staff
Sharon Arnold, PhD, ASPE, Exec. Staff Director
Rebecca Hines, MHS, NCHS, Exec. Secretary

NCVHS Staff
Maya Bernstein, JD, ASPE/OSDP
Lorraine Doo, MPH, CMS
Grace Singson, PharmD, ASPE
Marietta Squire, NCHS

Invited Speakers
Sara Rosenbaum, JD, PhD, GWU
Lisa Satterfield, MS, MPH, American College of Obstetricians and Gynecologists
Monica Edwards, JD, In Our Own Voice: National Black Women's Reproductive Justice Agenda
Elizabeth Mosley, PhD, MPH, University of Pittsburgh
Jake Laperruque, JD, Center for Democracy and Technology
Richard Salgado, JD, Stanford University
Deven McGraw, JD, MPH, Invitae
Travis Hoppe, PhD, NCHS
Greg Singleton, HHS, ICIO, IO
Gil Alterovitz, PhD, FACMI, FAMIA, VA RAIO
April Foreman, PhD, LP, VA
Farhan Khan, MS, FDA
Lakshmi M. Grama, MA, MLS, NCI, NIH
Asif Rizwan, PhD, NIH, NHLBI
Kathryn Marchesini, JD, ONC, HHS

In addition to those individuals who presented virtually during the meeting (listed above), 434 people followed the meeting online.

ACTIONS

1. The Committee plans to develop a draft of its 2023 Report to Congress by September 30, 2023, and the Committee plans to present this report at the next Full Committee meeting on November 29-30, 2023.

—DAY ONE—

Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer

Ms. Hines invited NCVHS members and speakers to introduce themselves and state any conflicts of interest pertaining to the meeting. Mr. Ferguson noted that his organization, Kaiser Permanente, submitted a response to the Request for Information (RFI) regarding the implementation of the International Classification of Diseases, 11th Edition (ICD-11); thus, Mr. Ferguson recused himself from discussions regarding ICD-11. As a member of the Alabama Department of Public Health, Ms. Donald recused herself from presentations and discussions regarding reproductive health and privacy. No other members stated any conflicts of interest.

Ms. Hines highlighted the upcoming ICD-11 expert roundtable meeting on August 3. This meeting will be available to attend both virtually and in-person, with the in-person meeting held at the Hubert H. Humphrey Building in Washington, DC.

Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members and invited speakers to the meeting and reviewed the meeting agenda.

New Member Update—Jacki Monson, Chair

Ms. Monson introduced four new NCVHS Committee members: Catherine Donald, MBA; Michael Hodgkins, MD; R. Lenel James, MBA; and Steve Wagner, MBA.

Update from the Office of the Assistant Secretary for Planning and Evaluation (ASPE)—Sharon Arnold, Executive Staff Director

Ms. Arnold began her presentation by reiterating the overarching goals of Department of Health and Human Services (HHS), which are: (1) protect and strengthen equitable access to high quality affordable health care; (2) safeguard and improve national and global health conditions and outcomes; (3) strengthen social well-being, equity, and economic resilience; (4) restore trust and accelerate advancements in science and research for all; and (5) advance strategic management to build trust, transparency, and accountability. These overarching goals guide the efforts of the many different components of HHS.

COVID-19 Updates

On May 11, the COVID-19 public health emergency (PHE) declaration ended. However, HHS recognizes that COVID-19 is still a public health priority, and HHS continues to strengthen U.S. preparedness and response efforts and safeguard the health and well-being of all Americans.

FDA Vaccines and Related Biological Products Advisory Committee met in June to make recommendations to FDA regarding updated COVID-19 vaccines for use beginning in the fall. This Committee recommended that FDA use monovalent vaccines this fall rather than bivalent vaccines. In April, HHS announced an initial investment of $5 billion in Project NextGen, which seeks to accelerate and streamline the rapid development of the next generation of vaccines and treatments through public-private collaborations.

The end of the PHE declaration also ended HHS's authorization to collect some COVID-19 data (e.g., viral genomic data from positive laboratory COVID-19 tests), although HHS continues to collect other relevant data such as COVID-19 associated deaths and emergency department visits. HHS also continues to perform wastewater surveillance of SARS-CoV-2 variants and COVID-19 vaccination coverage, and these data are updated as available on the CDC COVID Data Tracker.

The end of the PHE declaration also ended the requirement for public insurance companies to provide no-cost coverage for COVID-19 vaccines and testing (both laboratory and at-home testing). Thus, payment coverage and access to vaccines and testing may vary between insurers and plans. Medicaid will continue to provide no-cost coverage for COVID-19 tests and vaccines until the end of September, after which coverage and cost-sharing will vary between state Medicaid programs. Under most private insurance plans, preventative vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) will remain available at no-cost to patients. For people without insurance, CDC announced the HHS Bridge Access Program for assistance in gaining access to COVID-19 vaccines and tests.

Sexually Transmitted Infections (STIs) Federal Implementation Plan

On June 8, HHS released the inaugural Sexually Transmitted Infections Federal Implementation Plan, which highlights more than 200 actions across federal and state agencies to combat STIs in the U.S. This plan also emphasizes collaboration, expanding access to care, and developing new tools and therapies to combat STIs while focusing on health equity and measuring progress toward set goals.

Respiratory Syncytial Virus (RSV) Update

People 60 years and older can now receive a single-dose vaccine against RSV. Furthermore, FDA has approved a medication for the prevention of RSV in neonates and infants born during – or entering – their first RSV season.

Opioid Misuse PHE Update

On July 7, Secretary Becerra renewed the opioid PHE declaration for another 90 days. In March, FDA approved Narcan (i.e., naloxone) nasal spray for non-prescription, over-the-counter usage. This approval will make Narcan available directly to consumers, making this life-saving medication more widely available for preventing deaths due to opioid overdoses.

The Centers for Medicare and Medicaid Services (CMS) recently released an evaluation report on the maternal opioid misuses model. Similarly, collaborative research between CMS, CDC, and the National Institute on Drug Abuse (NIDA) revealed that the expanded availability of opioid use disorder-related telehealth services and medications during the COVID-19 pandemic lowered the likelihood of fatal drug overdose among Medicare beneficiaries.

Expanding Health Care Coverage and Access

In May, CMS approved a state plan amendment that allows South Dakota to expand Medicaid coverage to residents with incomes up to 233 percent of the federal poverty level. With the addition of South Dakota, 39 states and the District of Columbia have now expanded Medicaid access under the Patient Protection and Affordable Care Act (ACA). Similarly, since December 2022, five additional states and the U.S. Virgin Islands have extended postpartum coverage under Medicaid and Children's Health Insurance Program (CHIP), bringing the total number of states with this expanded postpartum access to 35.

Rulemaking Activities

HHS recently released a Notice of Proposed Rulemaking (NPRM) regarding protecting access and patient privacy for reproductive health care. HHS received almost 26,000 comments in response to the NPRM, including a comment letter from NCVHS. HHS is currently reviewing these comments prior to proceeding to the next steps of rulemaking.

Earlier in July, the Office for Civil Rights (OCR) and the Assistant Secretary for Financial Resources announced an NPRM to affirm civil rights and equal opportunity for people nationwide in HHS-funded programs and services. If finalized, the proposed role will protect recipients of these programs and services from discrimination due to receiving these services.

In November 2022, OCR and the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed changes to the confidentiality of substance use disorder patient records under 42 CFR Part 2 to protect patient privacy and records concerning treatment related to substance use from unauthorized disclosures. The proposed rule builds on HHS efforts to ensure and expand access to health care and social services.

Discussion

Dr. Mays expressed concern about the reduction in public health data collection resulting from the end of the PHE declaration, and she noted that NCVHS previously made recommendations regarding public health data collection to better prepare for the next pandemic or other PHE. She also expressed concern about potential reductions in budgets for public health data modernization efforts. Ms. Arnold replied that HHS is leading a concerted effort across HHS components (e.g., CMS, CDC) to improve data collection for public health surveillance, including a data modernization initiative at CDC. She recognized the budgetary uncertainty over the next few years and reiterated HHS's commitment to data modernization.

Workgroup on Timely and Strategic Action to Inform ICD-11 Policy—Jamie Ferguson and Margaret Skurka, Workgroup Co-Chairs

ICD-11 was adopted by the World Health Organization (WHO) in 2019 and became effective beginning on January 1, 2022. NCVHS is currently evaluating three components of ICD-11: (1) mortality reporting (e.g., cause of death); (2) morbidity coding (e.g., specific diagnoses) for health care and public health purposes; and (3) morbidity coding as a HIPAA-mandated medical code set for health care billing and payment. As a member of WHO, the U.S. is treaty-bound to implement ICD-11 for mortality reporting, whereas usage of ICD-11 for morbidity reporting is not required.

The NCVHS ICD-11 Workgroup has identified three goals for ICD-11 implementation in the U.S.:

1) Avoid a repeat of the protracted and costly U.S. transition from ICD-9 to ICD-10 by identifying lessons learned from the ICD-10 planning process and transition, as well as how implementing ICD-11 will differ from ICD-10.
2) Reach consensus on research questions to evaluate costs and benefits of transitioning from ICD-10 to ICD-11 for both mortality and morbidity reporting as well as costs and benefits of *not* using ICD-11 for morbidity reporting.
3) Identify key topics and messages to foster early engagement and preparation among health care industry stakeholders for ICD-11 implementation.

Based on these goals, NCVHS is focusing on developing recommendations to information development of sound U.S. policy for implementing ICD-11.

As part of these efforts, NCVHS held an ICD-11 expert roundtable meeting in August 2019 to discuss relevant issues and concerns regarding ICD-11 implementation. In November 2019, NCVHS recommended that HHS (1) evaluate impacts of different approaches for implementing of ICD-11 for mortality and morbidity classification and (2) provide timely leadership on strategic outreach and communications to the healthcare industry regarding ICD-11 implementation. However, the COVID-19 pandemic hindered further evaluation of ICD-11. To restart this process, NCVHS sent a recommendation letter to HHS in September 2021 with similar recommendations to the 2019 letter.

On December 7, 2022, NCVHS established the ICD-11 Workgroup, which now includes 17 members from eight different agencies outside of NCVHS. In the spring of 2023, NCVHS completed an environmental scan of published literature on ICD-11 to identify research gaps. Most of the ICD-11 studies identified in the environmental scan were conducted outside the U.S., which highlights the need for more research on ICD-11 in the U.S. On June 13, 2023, the ICD-11 Workgroup issued an RFI regarding ICD-11 implementation, and the Workgroup received 18 responses.

The August 3 roundtable meeting has two objectives: (1) identify ICD-11 adoption and implementation issues and research questions that are most critically important to study in order to inform ICD-11 policy recommendations and (2) obtain inputs from stakeholders to develop collaborative plan – including a potential timeline and necessary resources – for ICD-11 implementation and establish an ongoing ICD-11 community of interest.

The roundtable meeting will also discuss key points from RFI responses and a potential public/private collaborative to coordinate ICD-11 research and identify ways to improve coordination with WHO for requesting changes to ICD-11. The roundtable meeting will discuss potential benefits and costs associated with ICD-11 implementation, as well as which benefits of ICD-11 are most relevant for different stakeholders (e.g., clinicians, insurers) and how many relevant diagnostic classification codes currently used in the U.S. align with existing ICD-11 stem codes. Roundtable participants will also identify key research needed to determine whether the U.S. will not require a full clinical modification (CM).

Following the roundtable meeting, the ICD-11 Workgroup will develop a meeting summary and as well as a workgroup summary with conclusions, insights, observations, and findings regarding ICD-11 implementation.

Discussion

Automated Coding
Mr. Ferguson noted that the ICD-11 Workgroup is also examining impacts of ICD-11 adoption on automated coding. Because ICD-11 was developed upon the same foundation of clustered coding as Systemized Nomenclature of Medicine – Clinical Terms (SNOMED-CT), ICD-11 stem codes should allow for automated coding, but this automated coding capability will likely depend on future modifications of ICD-11.

Revision Requests
Ms. Hines noted that WHO is currently accepting requests for revisions to ICD-11, and individuals and groups from the U.S. are already sending revision requests to WHO. She expressed concern that the multitude of revision requests may lead to revisions that conflict with each other or impact ICD-11's design. Mr. Ferguson agreed with the concern and noted that the ICD-11 Workgroup appreciates the need for the U.S. to improve coordination of ICD-11 revision requests among U.S. stakeholders to mitigate these concerns.

Coordination with WHO
Dr. Mays asked about how NCVHS and other federal agencies interact with WHO regarding ICD-11 implementation. Mr. Ferguson responded that a WHO representative will attend the August 3 expert roundtable meeting, and the U.S. federal government has a delegation that participates in WHO Collaborating Centres and provides input on ICD-11 maintenance and revisions.

Review of NCVHS Recommendations on ICD-11
Dr. Watzlaf encouraged NCVHS Committee members and meeting attendees to review the 2019 and 2021 NCVHS recommendation letters regarding ICD-11 implementation, which are available on the NCVHS website. Dr. Watzlaf will also send a link for the RFI responses to Committee members. She noted that, if the ICD-11 Workgroup is authorized during the next fiscal year (FY), the Workgroup may issue another RFI following the expert roundtable meeting as an additional opportunity for health care stakeholders to provide inputs on ICD-11 implementation.

Implementation of ICD-11 for Mortality Reporting in the U.S.—Robert N. Anderson, PhD, Chief, Mortality Statistic Branch, CDC, National Center for Health Statistics (NCHS)

Current mortality reporting through the National Vital Statistics System (NVSS) is conducted through collaborations between NCHS and state vital record agencies. NCHS receives relevant information (e.g., underlying cause of death, demographic data) from death certificates from state registrars, after which NCHS compiles this information for national mortality statistics (e.g., death rates, leading causes of death).

Coding Process

Currently, death certificates do not contain ICD-10 codes for cause of death; some states attempted to begin listing relevant ICD codes, but limited state budgets prevented widescale adoption. Thus, NCHS extracts and codes causes of death and contributing conditions based on different text sections on death certificates. Most of this coding is automated and performed by MedCoder, which was a successor to the Mortality Medical Data System (MMDS) software. MedCoder is currently able to automatically code approximately 85 percent of records, with the remainder of records requiring manual coding. Automated coding can be performed in less than a day, whereas manual coding typically requires 1-2 weeks.

For automated coding, MedCoder uses machine learning (ML) and natural language processing (NLP) applications to extract relevant data from death certificate text fields, after which MedCoder uses rules-based programming originally developed for MMDS to assign relevant ICD-10 codes. MedCoder also stores the corresponding text field for quality control and manual audit purposes.

Mortality reporting using ICD-11 will occur through the ICD-11 for Mortality and Morbidity Statistics (ICD-11-MMS) system. This system is based upon specifications supplied by WHO.

Implementation Tasks

ICD-10 was implemented in the U.S. for mortality reporting in 1999, which was several years after other countries implemented ICD-10. The overall implementation process took seven years to complete, and much of the implementation time and expenses were involved in revising the automated coding software and decision tables for underlying cause selection.

Based on this experience, Dr. Anderson outlined six implementation tasks for implementing ICD-11 for mortality reporting:

1) **Revision of automated coding system**, including the underlying decision tables as well as causal and modification relationships. To revise decision tables, NCHS is collaborating with the Iris Institute, which is a collaborative effort across seven countries that focuses on automated coding systems. Although the U.S. uses MedCoder rather than Iris software, the underlying decision tables and data dictionaries are the same, so NCHS is collaborating with the Iris Institute to develop an ICD-11 version of Iris software.
2) **Revision of coding instructions and training materials**, including instruction manuals for recording both multiple and underlying causes of death. Nosologists and medical coders will need to be retrained for ICD-11, which will require development and preparation of training materials.
3) **Revision of database and computer specifications to accommodate ICD-11 codes**, including revisions to quality control specifications, data documentation, and file layouts. These revisions will also depend on the U.S. approach to implementing ICD-11 extension codes.
4) **Revision of standard tabulation lists**, including table programming and report formats.
5) **Comparability study of mortality coding using both ICD-10 and ICD-11**. This study would require coding a single year of mortality data using both ICD code sets using both automated and manual coding processes. This study will also identify whether changes between ICD-10 and ICD-11 impact longitudinal cause of death data.
6) **Communication plan and outreach materials** for both technical and non-technical audiences, including (1) vital registration jurisdictions; (2) federal, state, and local public health agencies; (3) statistical agencies; (4) researchers; (5) legislators; and (6) media.

Proposed Implementation Timeline

A working prototype of decision tables and data dictionaries for MedCoder and Iris software is expected by the end of October 2023. During 2024 and 2025, development on MedCoder or an alternative automated coding system will be conducted. During this same period, relevant tabulation lists, instruction manuals, and coding training materials will also be updated. Revisions to database and computer specifications will occur in 2026, and the comparability study will occur by 2027. Assuming all these tasks occur on schedule, full implementation of ICD-11 for mortality will occur no earlier than January 2028.

Discussion

International Differences in Implementing ICD-10

Mr. James asked why the U.S. has lagged behind other countries in implementing previous ICD versions. Mr. Anderson responded that varying record volumes account for some of these differences, as even the largest European countries do not have the volume of records that the U.S. needs to code. This larger volume of records also requires the U.S. to use MedCoder or a similar automated coding system, and upgrading these automated coding systems also lengthens implementation timeframes. During the conversion between ICD-9 and ICD-10, both France and Sweden used automated coding systems. Both countries were not able to fully implement ICD-10 mortality reporting until 1998, only one year before full implementation in the U.S.

Parallel Implementation of ICD-11 for Mortality and Morbidity Reporting

Ms. Banks asked whether any of the implementation efforts for ICD-11 mortality reporting can also be applied for morbidity reporting. Mr. Anderson responded that differences in use cases between mortality and morbidity reporting present challenges for parallel implementation of ICD-11 mortality and morbidity reporting. Although mortality reporting focuses primarily on cause of death, morbidity reporting serves multiple purposes (e.g., diagnoses, billing, reimbursement). However, implementing ICD-11 for mortality reporting may identify useful lessons for morbidity reporting.

Mortality Reporting by U.S. Territories

Mr. Anderson noted that NCHS also performs ICD mortality coding for U.S. territories, although these territories often vary in how quickly or consistently they send death certificates and other relevant data to NCHS. In particular, NCHS has experienced previous challenges getting data from American Samoa and the U.S. Virgin Islands. Dr. Mays noted that NCHS provided funding to U.S. territories for data modernization efforts and asked whether this funding was spent. Mr. Anderson responded that many territories used this funding to implement electronic systems for recording mortality data. However, some U.S. territories have very small populations and correspondingly small numbers of deaths per year; thus, implementing electronic systems provides little return on investment for implementing these systems. NCHS is currently assessing potential electronic systems that can be used across U.S. territories to improve mortality data reporting.

Linking Mortality and Demographic Data

Dr. Mays asked about efforts to link mortality data with demographic and social determinants of health (SDOH) data. Mr. Anderson replied that the CDC National Violent Death Reporting System (NVDRS) captures some relevant demographic data based on coroner and police reports, providing some linkages between these data types for violent deaths. NCHS is also assessing mechanisms for establishing linkages between mortality reporting and large NCHS health care surveys (e.g., National Health and Nutrition Examination Survey [NHANES]).

Reproductive Care and Health Policy – Panel 1—Moderator: Melissa Goldstein, Subcommittee on Privacy, Confidentiality and Security Co-Chair

Sara Rosenbaum, JD, PhD, Professor Emerita, Milliken Institute of Public Health, George Washington University

Dr. Rosenbaum framed the other presentations in this panel by providing an overview of the impacts of the U.S. Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* on reproductive care and patient privacy. She highlighted that impacts of this decision can be viewed through three lenses:

1) **Elimination of constitutional right to privacy:** The 1973 decision in *Roe v. Wade* established the precedence of this right to privacy and acted as a buffer against many state laws that sought to regulate the private conduct and sensitive information of state residents. The overturning of *Roe v. Wade* now exposes citizens to many of these intrusive state laws, particularly regarding reproductive health care.
2) **Public health:** The *Dobbs* decision and subsequent enactment of laws restricting reproductive health care may potentially impact many public health measures, including maternal and infant mortality, interpersonal violence, poverty, maternal health, and family wellbeing. Understanding the public health impacts of the *Dobbs* decision will require multiple years of data collection across many studies. Furthermore, concerns over data privacy will likely hinder access and dissemination of relevant data for public health researchers.
3) **Medical care:** Following the *Dobbs* decision, many obstetricians, gynecologists, and other medical professionals may feel impaired to provide many forms of health care, including prescribing certain medications and treatments. In many states with reproductive health care restrictions, women with completely non-viable pregnancies are being forced to carry these pregnancies to term, which creates significant risks to those women's health. Multiple studies will be required to assess the impact of reduced medical care on health care, including turnover and staffing challenges among health care professionals.

Lisa Satterfield, MS, MPH, Senior Director, Health Economics & Practice Management, American College of Obstetricians and Gynecologists (ACOG)

Ms. Satterfield thanked Dr. Rosenbaum for her framing. She noted that ACOG has an anonymous site where members can anonymously report relevant stories of how the *Dobbs* decision has impacted their medical practices. Ms. Satterfield highlighted three stories:

First, a community obstetrician had a patient with an ectopic pregnancy in the patient's fallopian tube. Even though this obstetrician and the patient are located in a state that allows for treatment of ectopic pregnancies, the obstetrician was still hesitant to prescribe medications for the pregnancy due to concerns about potential prosecution. Instead, the obstetrician transferred the patient to another state for terminating the ectopic pregnancy. The obstetrician remains afraid of future prosecution, even though the treatment occurred in another state.

This story highlights the uncertainty many physicians face in the post-*Dobbs* landscape. When HHS issued guidance that the Emergency Medical Treatment and Active Labor Act (EMTALA) requires hospitals to provide emergency medical treatment for life-threatening conditions such as ectopic pregnancies and protects physicians for providing this treatment, Texas sued HHS over this guidance, creating further confusion.

The second story comes from a physician in a state that criminalizes abortion. The physician can refer patients to a colleague in a neighboring state. To avoid potential prosecution, both the physician and the colleague in the neighboring state do not document abortion or that the patient was pregnant. The physician emphasizes the difficulty of this decision to not document pregnancy as necessary to protect both patients and physicians.

In the third story, in response to laws prohibiting abortion, a hospital has a new policy for terminating life-threatening pregnancies that requires (1) a signed statement from another physician stating that a pregnancy threatens the life of the mother and (2) an additional signature from a neonatologist stating that the fetus cannot be resuscitated. These statements are required for any termination of a pregnancy,

including surgery to remove an ectopic pregnancy. This new policy is designed to protect the hospital from prosecution, but obtaining these statements delays treatment for potentially life-threatening conditions. Similarly, neonatologists are required to take time away from caring for critically ill newborns to sign these statements, even in cases where a fetus is clearly not viable (e.g., an ectopic pregnancy at six weeks). This requirement also erodes trust in the profession of obstetrics and gynecology by implying that other types of professionals have more authority than obstetrics and gynecology.

Ms. Satterfield concluded her remarks by highlighting challenges being encountered in medical coding. Many relevant ICD-10 and Current Procedural Terminology (CPT) codes for lost pregnancies, including miscarriages and ectopic pregnancies, include the word "abortion" in the code description. Thus, many physicians do not include relevant ICD-10 and CPT codes in these cases for fear of prosecution or litigation.

Monica Edwards, JD, Director of Policy and Advocacy, In Our Own Voice: National Black Women's Reproductive Justice Agenda

Ms. Edwards began her remarks by describing In Our Own Voice: National Black Women's Reproductive Justice Agenda, a national/state partnership that collaborates with many state-based organizations such as Spark: Reproductive Justice Now, the Alfiya Center, Women With a Vision, SisterLove, Inc., Black Women for Wellness, SisterReach, Black Women's Health Imperative, and New Voices for Reproductive Justice to serve Black women, girls, and gender-expansive people.

In Our Own Voice: National Black Women's Reproductive Justice Agenda seeks to amplify the voices of Black women, girls, and gender-expansive people and secure reproductive justice for all people. Ms. Edwards defined "reproductive justice" as a human rights framework focused on the right to have (or not have) children, to parent children, and to live in safe and sustainable communities.

Ms. Edwards emphasized that many marginalized communities lacked access to abortion prior to the *Dobbs* decision due to limited access and restrictions such as the Hyde Amendment, mandatory ultrasounds, mandatory waiting periods, and parental involvement laws for patients under 18. Black women and gender-expansive people have always been denied control over their own health decisions, as shown by slavery, medical experimentation on Black women, continuous antiabortion restrictions, and laws restricting or forbidding gender-affirming care. Black women and gender-expansive people, along with many other marginalized communities, have significant medical mistrust due to this lack of patient agency.

Ms. Edwards described how many state-based partners of In Our Own Voice: National Black Women's Reproductive Justice Agenda are located in states in the South and Midwest, where abortion is banned or significantly restricted. Compared to the rest of the U.S., many of these states also have higher maternal mortality rates, lower Medicaid coverage, and greater obstacles to healthcare access for many marginalized communities.

Ms. Edwards described her experiences growing up in Alabama and argued that the Alabama state government frequently makes decisions in the best interest of those in power rather than of most state residents. Compared to even other countries, Alabama has one of the highest per capita incarceration rates in the world. In 2020, during the midst of the COVID-19 pandemic, Alabama spent more than $1 billion to build a new prison system in Montgomery, and the state continues to spend millions more on prison construction.

Alabama is one of many states where abortion is now illegal, and Attorney General Steve Marshall recently suggested using the state's chemical endangerment law to prosecute women who use mifepristone, a synthetic steroid commonly used for medically induced abortions. Alabama has also made national news for prosecuting and convicting women for lost pregnancies. In 2019, Marshae Jones, a Black woman in Alabama, was shot by a coworker and lost her pregnancy, after which she was arrested and charged with manslaughter. In 2018, Jessica Lindsey was sentenced to prison after pleading guilty under the chemical endangerment law in Alabama for using an illegal substance while pregnant.

In 2022, In Our Own Voice: National Black Women's Reproductive Justice Agenda released its revised policy agenda titled *Reimagining Policy in Pursuit of Black Reproductive Justice*. This document urges lawmakers and federal agencies to use all means available to protect the rights and health care access of Black women and gender-expansive people, including privacy protections. Ms. Edwards closed her remarks by urging NCVHS, federal agencies, and lawmakers to approach relevant issues such as privacy protections from a reproductive justice framework that focuses on people most impacted by the *Dobbs* decision.

Elizabeth Mosley, PhD, MPH, Assistant Professor of Medicine, Center for Innovative Research on Gender Health Equity, Bixby Center for Global Reproductive Health, University of Pittsburgh

Dr. Mosley discussed the challenges of conducting research on abortion following the *Dobbs* decision. She began her presentation by emphasizing the importance of abortion research to optimize reproductive health outcomes and reduce maternal mortality. Abortion research is particularly important following the *Dobbs* decision, which created a significant shift in reproductive health care access. Abortion is now banned or significantly restricted in more than half of U.S. states, where 25 people who are capable of becoming pregnant live.

Abortion research includes patients who use abortion care, patients who face barriers and never use abortion care, and people who self-manage their abortions outside of the health sector. Abortion research also involves longitudinal studies that follow pregnancies and outcomes following the end of those pregnancies. This research employs secondary analyses of health records data and medical claims data as well as primary data collection such as self-report surveys and in-depth interviews.

Dr. Mosley also emphasized that restrictive abortion policies are only one aspect of abortion stigma, which is the social process of assigning negative attributes to and then discriminating against anyone associated with abortion. This stigma poses challenges and risks for researchers due to the subject of their research. The post-*Dobbs* landscape poses new challenges for collecting, analyzing, and storing sensitive and identifiable data.

The *Dobbs* decision and subsequent legislation prohibiting or restricting abortion in many states creates uncertainty about protecting research participants and the institutional review board (IRB) review process. Dr. Mosley provided an example on a multi-state longitudinal study on pregnancy outcomes that includes in-depth interviews. This study includes sites in Texas and Tennessee, where abortion is illegal. When researchers sought IRB approval, IRB members raised questions about the study's risk mitigation strategy for conducting interviews in these states, including protection of interview audio files and whether researchers are at risk of civil or criminal penalties.

However, other IRBs do not show a similar level of concern. Dr. Mosley provided another example of a study conducted in Tennessee on reproductive health care services provided by doulas. Even though the study involves in-depth interviews with doulas, including those who provide abortion information and

support, the IRB deemed the study exempt from IRB oversight based on perceived low risk to doulas participating.

Research data security has typically been ensured through NIH Certificates of Confidentiality, which prohibit the disclosure of identifiable and sensitive research information to anyone not connected to the study except when the participant consents to this information being disclosed. This prohibition on disclosure has some exceptions for certain cases such as child abuse or participants threatening harm to themselves or others. Many states with fetal personhood laws classify abortion as child abuse; thus, these states may now seek access to research records under the exception for child abuse.

Abortion researchers may find themselves at potential legal risk. For example, researchers studying pregnancy and abortion often provide resource sheets to study participants, which often include resources for pregnancy services and abortion. States that criminalize aiding and abetting abortion (e.g., Idaho) may argue that providing this information constitutes aiding and abetting abortion. Similarly, a researcher conducting interviews with pregnant women may name nearby out-of-state abortion providers, which may also be classified as aiding and abetting.

Dr. Mosley and her colleagues have recently mitigated many of these issues by consulting with reproductive rights legal experts throughout study design. Many studies also completely anonymize study data and link data to participant identification numbers rather than any identifiable information (e.g., participant name). Dr. Mosley stressed the need for additional support and guidance, including standardized requirements and procedures for IRBs and data privacy protections.

Discussion

Usage of Anonymized Study Data

Dr. Watzlaf asked for additional detail on how researchers analyze completely anonymized data and detriments resulting from this anonymization. Dr. Mosely noted that completely anonymizing study data often prevents researchers from following up with specific participants. Some files (e.g., voice recordings) are simply deleted after use if they cannot be completely deidentified. Researchers also stopped collecting some data such as participant ZIP codes due to reidentification concerns, and Dr. Mosley's research group is currently collaborating with the Digital Defense Fund to identify and mitigate potential reidentification risks. Dr. Mosley emphasized that the risks to both participants and researchers far outweigh the research benefits of using identifiable research data.

Ms. Hines noted that participant and researcher concerns may now also impact NCHS data collection, particularly the National Survey of Family Growth (NSFG), given its focus on pregnancy outcomes. She expressed concern about people refusing to participate in NSFG given legal uncertainty and fear about potential prosecution.

Dr. Hodgkins suggested that researchers can also explore conducting studies with synthetic data derived from real-world data for protecting participants. Dr. Mosley agreed and noted that her research group is exploring a similar approach of creating amalgamations of qualitative interview data across participants to reduce reidentification risk.

Guidance and Standard Framework for Participant Privacy

Dr. Mosley reiterated the need for standardized guidance for IRBs regarding study data involving reproductive health care and gender-affirming care. Currently, many IRBs simply stop or prohibit sensitive studies when researchers – many of whom are not legal experts – cannot fully respond to all potential

legal scenarios. Standardized guidance and stronger participant privacy protections can enable researchers to effectively respond to IRB concerns.

Vulnerable Population Designation

Dr. Watzlaf noted that human subject research regulations include specific designations for vulnerable populations (e.g., minors) that have additional IRB considerations and privacy protections in research. She suggested potentially classifying pregnant people as well as transgender and nonbinary people to provide additional protections and provide a more standardized assessment approach for IRBs. Dr. Mosley expressed concern that classifying these groups as vulnerable populations may exacerbate IRBs' denial of any studies in these populations and reiterated the need for standard guidance from HHS instead.

Dr. Alison Cernich expressed additional concern about classifying pregnant people as vulnerable populations, which may impact clinical trials for therapeutics. Many pharmaceutical companies already exclude pregnant and lactating people from clinical trials, even in the absence of any evidence for increased risk in these groups. This exclusion results in a lack of relevant efficacy or risk data for pregnant and lactating people. Classifying pregnant people as a vulnerable population may exacerbate this exclusion from clinical trials.

Impacts of *Dobbs* Decision on Health Care

Ms. Bernstein asked how the *Dobbs* decision has impacted on the pipeline of new health care professionals and researchers. Ms. Edwards responded that some medical students are still interested in reproductive health care, but others are switching their focus to other areas of medicine. Ms. Satterfield agreed and noted that many obstetrics and gynecology studies are no longer accepting residency in states that restrict or ban abortion. Ms. Edwards noted that some states (e.g., Alabama) restrict information that physicians can provide patients, which is creating uncertainty and burdens for many primary care providers providing other forms of reproductive and preventative health care (e.g., Pap smears). The large amount of misinformation regarding birth control, including the misperception that some forms of birth control (e.g., intrauterine devices [IUDs]) cause abortion, is causing many physicians to express concern about discussing birth control with patients.

Reproductive Information and Technology Policy – Panel 2—Moderator: Valerie Watzlaf, Subcommittee on Privacy, Confidentiality and Security Co-Chair

Jake Laperruque, JD, Deputy Director, Security and Surveillance Project, Center for Democracy and Technology

Mr. Laperruque began his remarks by providing an overview the Center for Democracy and Technology, which seeks to ensure technology supports democracy and civil rights. This organization recognized that the *Dobbs* decision would create a significant shift in technological threats to civil rights as many states seek to monitor the medical choices and activities of many marginalized groups (e.g., pregnant women, transgender people). In response, the Center for Democracy and Technology created a task force to help advise companies on different legal issues and another task force to monitor data privacy concerns.

The Center for Democracy and Technology also submitted a response to the NPRM on reproductive health care. Mr. Lapperruque outlined X recommendations from this NPRM response:

1) **Requirements for warrants to access health care data should be significantly higher than current requirements.** Recently, members of Congress, led by a group of 17 senators and over

two dozen members of the House of Representatives, sent a letter to the Biden administration making a similar request.

2) **Law enforcement access to health data should be limited to a specific purpose and not shared or disseminated.** Law enforcement should be required to sign a certification under penalty of perjury with additional enforcement mechanisms such as "fruit of the poisonous tree" clauses (i.e., illegally obtained evidence is inadmissible in court).
3) **Patient data protections should be extended to all types of health care rather than limited to reproductive health care**. Extending these privacy protections will also protect other forms of health care that are being limited by states (e.g., gender-affirming care).
4) **Additional safeguards are needed regarding the sharing of electronic health records (EHR), including deidentified records, for research.** Sharing of EHRs should be limited to HIPAA-covered entities (CEs), and patients should have the ability to opt out of having their health data for research.
5) **HHS should incentivize organizations to locate their EHR servers and infrastructure in states with "shield laws"** (i.e., laws prohibiting sharing of protected health information [PHI] to law enforcement from other states). Locating data storage in these states may provide additional protection against PHI disclosure.

Deven McGraw, JD, MPH, Lead, Data Stewardship and Data Sharing, Invitae

Ms. McGraw began her remarks by providing an overview of Invitae, which provides prenatal genetic testing for genetic diseases and fetal abnormalities upon physician request. Following the *Dobbs* decision, Invitae has expressed concerns about protecting patient data out of concern about states using these data to identify terminated pregnancies. Many state laws that prohibit abortion do not contain exceptions for severe fetal abnormalities, which may lead law enforcement agencies to investigate health care providers for patients with positive or uncertain genetic test results.

Ms. McGraw noted that the *Dobbs* decisions and laws restricting gender-affirming care are exposing many limitations in HIPAA protections, and law enforcement can use these limitations to circumvent privacy protections. For example, Tennessee law enforcement subpoenaed health records for all transgender patients at Vanderbilt University Health Center to ostensibly assess compliance with "appropriate care guidelines." Once healthcare data are shared outside of HIPAA CEs, federal law has few protections regarding subsequent sharing and disclosure of these data.

These concerns need to be balanced against potential impacts of not sharing relevant health information between health care providers, which may significantly impair patient care. Ms. McGraw expressed concern that patients may opt out of sharing all of their health data without understanding the impacts of this lack of sharing, including challenges coordinating care between physicians. One potential solution is providing patients with more granular choices about sharing specific types of data.

Richard Salgado, JD, former Director of Law Enforcement & Information Security, Google
Lecturer, Stanford University Law School

Mr. Salgado began his remarks by providing an overview of his experience of consulting communication services providers on compliance with data privacy laws, particularly in response to requests from law enforcement agencies. Many large communications providers (e.g., cellular service carriers) have data for millions of users and receive requests from law enforcement agencies from countries around the world. These requests are associated with different legal systems and criminal statutes, which can create significant burden on communications services providers to manually review and respond to all requests.

Most subpoenas and law enforcement requests contain little detail on the case or reasons for the information requested, and communication services providers typically have no legal standing to require additional detail from law enforcement. Thus, communication services providers are often unable to determine whether subpoenas are for invalid or prohibited reasons.

Some large communication services providers have created electronic interfaces for law enforcement agencies to submit records requests. These interfaces can ask law enforcement agencies specific questions about the subpoena and include attestations about prohibited usages of personal data. However, not every services provider has this type of interface. Furthermore, current laws allow law enforcement to subpoena records for one potential crime and then identify a completely different crime in those data.

Many communication services providers have also partnered with non-governmental organizations (NGOs) to assist with evaluating and responding to subpoenas for user data. Some communication services providers have also stated that they will scrutinize broad requests for user data and notify users when their information has been subpoenaed (when allowed by the subpoena). However, Mr. Salgado stressed that these companies receive a high volume of law enforcement requests for user data, and this volume poses challenges to complying with shield laws and the proposed Privacy Rule to protect reproductive health care data.

Discussion

Notifying Users about Warrants

Dr. Watzlaf asked how communication services providers provide notice to users when their data has been subpoenaed, particularly when warrants contain relatively little information. Mr. Salgado responded that companies can notify users as long as warrants do not include gag orders that prohibit notifying users. Notifying users about warrants can enable these users to obtain counsel and prepare for potential civil or criminal litigation. Depending on information in the warrant, communication services providers may also be able to notify users if the warrant relates to PHI.

Electronic Interfaces

Ms. Goldstein asked whether HIPAA CEs can use electronic interfaces for law enforcement requests similar to those interfaces used by communication services providers, and whether these interfaces could reduce the burden of attestation under the proposed HIPAA Privacy Rule. Mr. Salgado responded that the interfaces mainly change *how* user information is requested by law enforcement. These interfaces could require law enforcement personnel to certify an attestation when submitting a request.

Attestations

Mr. Laperruque reiterated the need for robust enforcement of attestations such as certifying attestations under the penalty of perjury and "fruit of the poisonous trees" clauses. Attestations should also be 1-2 sentences and clearly worded. Mr. Laperruque suggested establishing clear enforcement mechanisms for attestations under a single federal agencies or other enforcement body.

Dr. Hodgkins expressed concern about whether all health care providers are knowledgeable enough to discern what information could be potentially related to reproductive health care (e.g., last menstrual period). Thus, some health care providers may mistakenly attest that information is not related to reproductive health care in these cases, reducing the effectiveness of attestations in protecting access to reproductive health care. Dr. Hodgkins also expressed concern that increasing amounts of PHI are now held by entities not covered by HIPAA such as health applications (e.g., period tracker apps) and non-HIPAA organizations that provide or assist with gender-affirming care.

Updates / NCVHS Workplan Development: Subcommittee on Privacy, Confidentiality and Security—Melissa Goldstein and Valerie Watzlaf, Co-Chairs,

Dr. Watzlaf presented an overview of past work by the Subcommittee on Privacy, Confidentiality and Security:

- NCVHS Comment Letter – NPRM on HIPAA Privacy Rule to Support Reproductive Health Privacy (2023).
- Environmental Scan—Ongoing and Emerging Issues in Privacy and Security in a Post COVID-19 Era (2022).
- Letter of Recommendations regarding Privacy, Confidentiality, and Security Considerations for Data Collection and Use During a Public Health Emergency (2022).
- Letter of Recommendations to Strengthen Cybersecurity in Healthcare (2022).
- Health Information Privacy Beyond HIPAA: A Framework for Use and Protection (2019).
- Letter of Recommendations for HHS Actions to Improve Privacy Protection for Health Information not Subject to HIPAA Regulations (2019).
- Letter of Recommendations on Deidentification of Protected Health Information under HIPAA (2017).

In 2023, the focus of the Subcommittee on Privacy, Confidentiality and Security efforts has shifted to several key areas: (1) panels on legislative developments in data privacy and on current issues in cybersecurity; (2) environmental scan—privacy and security emerging issues; (3) outreach with the Office for Civil Rights (OCR) for periodic check-in discussions; and (4) HIPAA and reproductive health privacy recommendations. The Subcommittee is also considering several ongoing initiatives that often intersect, allowing for potential mentions and connections across various letters and discussions. These include security topics such as (1) deidentification; (2) AI and machine learning (ML) tools (inferences from existing data requiring privacy risk assessments); (3) law enforcement access to and use of private information (e.g., reproductive health information); (4) HIPAA interactions with broader privacy laws that are under consideration; and (5) availability of data for public health purposes. Other privacy topics that the Subcommittee is considering include: (1) the impact of cyberattacks on health care systems and health care institutions; (2) security principles and safety for patients and consumers of medical/health-related devices, apps, electronic health information exchange (HIE) (e.g., interoperability, wearables, telehealth); (3) education and training of workforce on cybersecurity; and (4) cybersecurity vulnerabilities that lead to unavailability of data, devices, and systems.

Ms. Goldstein presented an overview of the Subcommittee's timeline and projected path forward. In the latter half of 2022, the Subcommittee convened expert panels for insightful discussions, laying the groundwork for future endeavors listed above. The first half of 2023 was dedicated to discussing a response to the NPRM on reproductive health care and patient privacy. As the Subcommittee moves into the third quarter of 2023, the Subcommittee's focus shifts toward the development of project scoping documents. These initial documents represent the first attempts at outlining the direction for upcoming projects. The Subcommittee will then engage in thorough discussions and revisions, aiming for the Full Committee's approval before embarking on new projects. The goal is to reach the stage where these recommendations take shape by the end of 2023, extending into the coming year.

Public Comment—Rebecca Hines, Executive Secretary and Designated Federal Officer

Dr. Tejas Sathe, University of California, San Francisco, stated that his work involves advocating for the use of unique device identifiers (UDIs) for medical devices, referencing an opinion piece suggesting that UDIs

should be included in billing claims as an incentive for health care systems to gather data from implanted devices. However, CMS cited the recommendations letter from the NCVHS on the Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions, dated July 14, 2023, that opposed including UDIs in billing claims. Mr. Sathe asked the Committee what the primary criticisms against including UDIs in billing claims are, as outlined in the NCVHS recommendation letter on the Updated Version of the X12 Standard for Claims and Electronic Remittance Advice Transactions, and how can he continue advocating for the inclusion of UDIs in a way that respects privacy, addresses concerns, and promotes NCVHS's objectives. Ms. Hines stated that the Committee is unable to respond during the public comment period, but the NCVHS Committee will be able to engage in this discussion at a later time.

Wrap Up and Adjourn—Jackie Monson, NCVHS Chair

Ms. Monson thanked Subcommittee staff members, invited speakers, and the NCVHS team for their support and adjourned the meeting.

—DAY TWO—

Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer

Ms. Hines invited NCVHS members and speakers to introduce themselves and state any conflicts of interest pertaining to the meeting. No attendees stated a conflict of interest.

Welcome Remarks / Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members, invited speakers to the meeting, and reviewed the meeting agenda.

Conversational AI Strategy and Standards Panel—Moderator: Travis Hoppe, PhD, Associate Director for Data Science and Analytics, NCHS, CDC, HHS

Travis Hoppe, PhD, Associate Director for Data Science and Analytics, NCHS, CDC, HHS

NCHS, which provides statistical information to guide actions and policies to improve the public health of the American people, employs numerous surveys and data collection systems, including population, provider, and historical surveys, as well as analyses of vital records. To enhance these collection systems, NCHS developed several AI resources and tools such as (1) Semi-Automated Non-response Detection for Surveys (SANDS), an open-access tool that helps researchers and survey administrators detect non-response in open-ended survey text; (2) MedCoder; (3) an algorithm that detects stimulant and opioid misuse and illicit use in electronic health records (EHRs); (4) Whisper, a versatile speech-to-text, commercial-grade, automatic speech recognition (ASR) model that has significantly improved the precision of transcribing over 20,000 hours of recorded interviews, resulting in a twenty-fold increase in detection accuracy; and (5) a private AI model for the detection of personally identifiable information (PII) in response to Freedom of Information Act (FOIA) requests.

Dr. Hoppe emphasized that the aim of the panel is to establish standards for ChatGPT, a specific conversational artificial intelligence (AI) chatbot created by OpenAI, but acknowledged the broader scope of generative AI and artificial intelligence as a whole. He highlighted the rapid pace of research and development in conversational AI, citing the example of ChatGPT-3.5 and ChatGPT-4.0 releases and stating the need to consider the future of AI technologies and their potential impact. Although ChatGPT

offers significant benefits, such as advancing medical education, generating research articles, and streamlining recordkeeping, it also has limitations, including a lack of context and nuance, potential perpetuation of systemic societal biases (e.g., analyses based upon biased datasets), privacy concerns, limited knowledge window, and the risk of incorrect medical information. For example, a chatbot designed to prevent eating disorders had unintended negative consequences (e.g., offering potentially harmful dieting advice) due to inadequate testing by its developers.

Greg Singleton, Chief Artificial Intelligence Officer, HHS, ICIO, IO

Mr. Singleton highlighted the importance of AI as "human insights at machine speed." This description refers to AI's ability to process large volumes of data quickly and efficiently, enabling humans to focus on more creative and challenging tasks while addressing the growing data volume and the limitations of human attention and productivity. Notably, AI holds promise for areas like drug discovery and technology advancement. However, AI also poses many risks, including potential perpetuation of racial, gender, and age biases. Therefore, striking the right balance between cautious regulation and harnessing AI's potential is essential. Mr. Singleton outlined the three primary focus areas for AI implementation at HHS: internal operations, HHS program implementation strategies, and the broader health sector. He explained that HHS is cautiously conducting assessments in each of these areas to identify opportunities and potential risks, aiming to gradually build AI capabilities while learning from each step.

Gil Alterovitz, PhD, FACMI, FAMIA, Chief AI Officer, Director, National Artificial Intelligence Institute (NAII), VA Responsible AI Official (RAIO)

The U.S. Department of Veterans Affairs (VA) is responsible for one of the largest integrated healthcare systems in the country, extending its services beyond U.S. borders to other countries. The National Artificial Intelligence Institute (NAII) is the preeminent organization for AI research, implementation, policy, and collaboration at the VA. NAII aims to leverage AI to improve Veteran care, including healthcare applications and benefits. NAII also regulates a wealth of knowledge and data, including genomic donations and EHRs, and coordinates thousands of medical facilities and clinicians. Therefore, the unique role of AI in natural language understanding and conversation is crucial for effective communication with Veterans and health care professionals.

Dr. Alterovitz noted that generative AI models can now produce varied responses to the same input, leading to both opportunities and risks. To navigate this challenge and develop new AI approaches, NAII created several strategy execution priorities, including (1) building a robust community and network around AI at VA; (2) prioritizing and investing in AI research; (3) reducing barriers to translating AI advances into real-world capabilities; (4) adopting an AI maturity model tailored to the VA's mission and needs; (5) providing subject matter expertise to the VA's mission and needs; and (6) providing subject matter expertise in AI research and development (R&D), implementation, and policy.

Dr. Alterovitz emphasized the importance of using AI to optimize large-scale processes and policies, thus enhancing efficiency across VA departments. For example, NAII developed a VA-specific trustworthy AI framework to integrate various existing frameworks and guidelines, with a capacity for collaboration with other agencies to share insights and best practices.

April Foreman, PhD, LP, Deputy Director of Technology & Innovations, Veterans Crisis Line Suicide Prevention, Office of Mental Health and Suicide Prevention, VA

Dr. Foreman highlighted the potential of conversational AI to provide support and innovation for suicide prevention, as traditional approaches and existing interventions like talk therapy are becoming insufficient for scaling suicide prevention efforts. The newly launched VA chatbot, which is both easily accessible and safe, represents a step toward reimagining Veteran support at VA. This initiative also indicates the need for innovative and visionary subject matter experts to drive similar advancements in suicide prevention efforts using conversational AI.

Farhan Khan, MS, Director of Operations and Delivery, FDA

Mr. Khan stated that his main responsibility as Director of Operations and Delivery is to manage data, ensuring its security, accessibility, and availability to users. He highlighted the importance of conversational AI, emphasizing that the quality of coding data used in AI systems is paramount. His main objective within FDA is to facilitate effective data management and storage, oversee the necessary platforms for data transfers, and ensure that quality data are accessible to the various applications and machines within FDA, including AI systems.

Lakshmi M. Grama, MA, MLS, Assoc. Dir., Dissemination & Digital Communications Office, NCI, NIH

During the COVID-19 pandemic, institutions like WHO and CDC used chatbots solely to effectively disseminate health information and counter misinformation. The National Cancer Institute (NCI) uses AI to enhance the Cancer Information Service and improve response quality and speed for contact center operators by creating personalized experiences. Additionally, NCI is considering the use of AI to support content creators in reviewing and updating vast amounts of medical literature. However, the current transition to conversational AI offers both potential benefits and concerns, including benefits from natural and interactive conversations, but also raises concerns about the trustworthiness of responses. Although large language models like ChatGPT have been used for scalable applications with small impact projects, government agencies need to approach this technology with caution, especially in scenarios where consequences are higher, and trust must be established and maintained.

Asif Rizwan, PhD, Program Director, National Heart, Lung, and Blood Institute (NHLBI), NIH

Dr. Rizwan highlighted the significant opportunities that generative AI can offer to the research community, emphasizing that the current understanding of its capabilities is the first step in AI adoption. For example, generative AI can play a crucial role in identifying patterns within research data, enabling scientists and researchers to formulate hypotheses based on those patterns.

NIH will continue to develop tools and support research initiatives aimed at harnessing the power of generative AI, with a goal to facilitate the identification of innovative and novel ways to enhance research processes and outcomes.

Kathryn Marchesini, JD, Chief Privacy Officer, Office of the National Coordinator for Health Information Technology (ONC), HHS

ONC is at the forefront of the HHS's health IT efforts and serves as a resource to the entire U.S. health system to support the adoption of AI technology and the promotion of nationwide, standards-based

health information exchange to improve health care. AI tools have shown promise for augmenting patient care in two areas:

1) Clinical AI tools, which have the potential to predict health trajectories of patients, recommend treatments, guide surgical care, monitor patients, and support population health management. These tools are at varying stages of maturity and adoption, but many have not achieved widespread use.
2) Administrative AI tools, which help reduce provider burden and increase efficiency by recording digital notes, optimizing operational processes, and automating laborious tasks. These tools are also at varying stages of maturity and adoption, ranging from emerging to widespread usage.

ONC aims to address fundamental and far-reaching potential challenges associated with predictive algorithms, including (1) reproducing or amplifying implicit and structural biases; (2) magnifying existing ethical, legal, and social concerns related to data collection and use; (3) reinforcing common, non-evidence-based practices or incorporating existing inexplicable differences in health outcomes; (4) perpetuating fundamental information asymmetries regarding an algorithm's quality, performance (including its fairness and validity); and (5) outputs or recommendations that are ineffective or unsafe.

ONC's Health IT Certification Program (Certification Program) establishes the Certification Program requirements as well as outcome-focused requirements known as "certification criteria" for health IT developers and Health IT Modules. ONC's Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule seeks to implement provisions of the 21st Century Cures Act and make updates to the Certification Program with new and updated standards, implementation specifications, and certification criteria. Implementation of the proposed rule's provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information, as well as information related to health equity. The proposed rule includes proposals to promote greater trust in the predictive decision support interventions (DSIs) used in healthcare to enable users to determine whether predictive DSI is fair, appropriate, valid, effective, and safe, and enable market competition.

Discussion

Conversational AI Potential in Government Services

Dr. Hoppe asked whether there are potential conversational AI innovations that will be transformative for state, local, or territory governments and how the federal sector can support these partners. Mr. Khan highlighted several helpful applications for conversational AI:

1) **Multi-language support:** conversational AI can overcome language barriers and enable citizens from diverse backgrounds to interact with government agencies and access services in their preferred languages.
2) **Emotional recognition and sentiment analysis:** conversational AI can analyze emotions expressed by citizens in interactions, helping government agencies understand public sentiment and improve services accordingly.
3) **Personalization and context retention:** conversational AI can personalize interactions based on individual preferences and previous interactions, leading to more tailored and effective services, such as in suicide prevention efforts.
4) **Suicide prevention:** conversational AI can play a crucial role in suicide prevention by identifying emotional cues and providing timely support to individuals in crisis.

5) **Reducing administrative overhead:** conversational AI can streamline administrative processes, reducing the burden on government agencies and enabling more efficient service delivery.

To support the implementation of conversational AI at the state, local, and territory levels, Mr. Khan suggested several strategies: (1) establishing a centralized platform that aggregates and providing access to government data, enabling efficient data sharing and utilization for conversational AI initiatives; (2) allocating resources and funding to advance research and development in conversational AI, ensuring the U.S. remains competitive in AI innovation; (3) developing clear guidelines and regulations for data sharing among government agencies to facilitate the responsible and ethical use of data in AI applications; and (4) providing standardized regulatory guidance for implementing conversational AI solutions, ensuring consistency and compliance across different government entities.

Technological Influences in Health Care

Dr. Hoppe asked whether there are technologies that are expected to significantly influence the VA's approach to health care. Dr. Alterovitz explained the intersection of different technologies and their potential applications, particularly in the context of VA health care:

1) **Deep learning and predictive models:** deep learning is a powerful tool for predictive modeling in health care. For example, deep learning is now being used to predict acute kidney disease hours before presentation of clinical symptoms, which can greatly improve patient outcomes.
2) **Human interaction:** compared to conventional forms of interactive technology, conversational AI can facilitate more natural interaction with users and provide valuable information.
3) **Health efforts and technology integration:** conversational AI has been used to enhance clinical trial matching and resource discovery. This use highlights the potential for technology integration to improve health care services and patient support.
4) **International collaboration:** AI enables international collaboration to advance technology in health care.

To further address these potential applications, NAII is hosting a summit on September 6-8, 2023, in Washington, D.C., to bring together AI experts from around the globe for insightful presentations and interactive discussions to address the future role AI in Veteran health care.

Ms. Grama added that generative AI has the potential to enhance digital experiences for individuals with disabilities. Although there have been previous attempts at automated audio descriptions and captions, many individuals with disabilities express that these solutions fall short of providing a comprehensive experience. With the emergence of large language models, the creation of more effective alternative text for images is becoming a reality, offering improved and more descriptive ways of conveying visual content. The pursuit of more inclusive digital experiences, especially in the realm of health communications, is not just important but essential to enable citizens with disabilities to engage in seeking health information.

Mr. Singleton stated that although precision medicine initiatives have long aimed to offer personalized medical insights, they often fall short of encompassing an individual's entire medical history and complex health factors. AI, with its ability to synthesize and analyze vast medical records, holds the potential to identify nuanced disease/health correlations that may be overlooked by humans due to limited knowledge or access to information and health records. This potential not only benefits individuals seeking personalized care but also extends to the medical literature domain. The technology's capability to identify rare cases and studies that diverge from prevailing trends could prove invaluable to clinicians seeking diverse perspectives. Furthermore, AI offers a gateway to harnessing alternative data modalities

beyond traditional text-based medical records and diagnostics. Medical data can encompass imaging, movement, or motion data from mobile phones, and voice data from audio recordings. These untapped data sources hold untold potential to augment medical practices. Pioneering endeavors include studies employing synthetic noses to identify Parkinson's disease through the detection of biomarkers and other compounds emitted by human bodies. Such signals, often unnoticed by conventional diagnostics, could be used to offer novel insights into health conditions. These alternative domains stand to revolutionize health care by leveraging diverse data sources for enhanced diagnosis and treatment.

Dr. Foreman noted that the intersection of computational linguistics and clinical psychology presents a remarkable opportunity to revolutionize mental health diagnoses. The challenge of achieving accurate and standardized mental health diagnoses is widely acknowledged, and bridging the gap between computational linguistics and clinical psychology offers a promising solution. Dr. Rebecca Resnik, President of The Maryland Psychological Association, envisions a solution wherein individuals could provide language samples to their health care providers for analysis. By harnessing the potential of advanced computational tools, it becomes possible to analyze language samples with a level of accuracy that surpasses traditional clinician-based diagnoses, which can transform the field of mental health assessment and treatment. Although the implementation of such an endeavor may pose challenges, the groundwork has been laid for exploring novel ways to utilize language data for improved mental health outcomes.

Ms. Banks asked whether AI could reduce the cost of modernizing health care data infrastructures. Mr. Singleton emphasized the significance of translational interfaces between systems, highlighting the potential to reduce labor-intensive work and improve overall efficiency. AI in health care may also mitigate impacts of labor shortages, reduce errors, and enhance patient care by automating tasks such as data entry and transcription. This empowerment of employees through AI tools can potentially increase productivity and improve patient outcomes.

Ethical AI Implementation

Dr. Hoppe asked about ways the government can protect patients from inappropriate medical decisions in health care. Dr. Foreman emphasized the multifaceted nature of ethical AI implementation, noting that implementation of AI tools should occur under careful scrutiny to ensure the safety and informed consent of users. Informed consent particularly becomes pivotal in health care AI, paralleling medical procedures during which patients understand risks and concerns prior to treatments. Thus, transparency in AI systems is key, especially when using “black box AI” (i.e., AI systems with internal workings that are invisible to the user).

Dr. Foreman added that AI applications should align with population health goals and be cautious when applying tools individually. Furthermore, the concept of a "human in the loop" review should be implemented as a safeguard for AI-driven decisions, ensuring critical human oversight. Ultimately, the true measure of AI success lies in tangible improvements to public health, quality of life, and ethical considerations rather than solely improvements in technical capabilities.

Dr. Alterovitz mentioned that an innovative approach, involving an IRB module, is currently undergoing piloting at NAII. The module aims to enhance the ethical evaluation of AI projects using existing IRBs to equip researchers with the right questions to ask and facilitate meaningful conversations. Notably, several studies were rejected based on the IRB module, citing a lack of transparency or concerns related to data collection. NAII is also working to establish an AI oversight committee, with a focus on operational applications to ensure responsible and ethical AI implementation.

Dr. Alterovitz stated that the current regulatory framework is centered around Executive Order 13960, which outlines nine principles for maintaining trustworthy AI. Agencies are required to have Responsible AI Officials who oversee the implementation of AI principles and report to the Office of Management and Budget (OMB). Additionally, Congress enacted several laws that align with this framework, reinforcing a regulatory structure similar to OMB. For example, as the use of AI within the VA grows exponentially with numerous cases, the VA is working to scale the analysis and oversight of these cases. This oversight involves creating oversight committees to manage AI cases not only at the central office level but also at various medical centers to ensure that AI use aligns with responsible and ethical principles. Mr. Singleton emphasized that concerns expressed by the Committee are taken with utmost seriousness, as AI officials across different branches of the federal government are actively engaging in finding comprehensive solutions. One of the principles outlined in Executive Order 13859 (Maintaining American Leadership in Artificial Intelligence) ensures that AI development aligns with core American values and prevents malicious actors from misusing AI technologies. Thus, federal efforts include the formulation of frameworks, strategies, and tools to effectively adapt and respond to potential AI misuse scenarios.

AI Training Datasets

Dr. Hoppe asked whether it is prudent for the government to prioritize the development of datasets specifically for training models (e.g., model cards, short documents that provide key information about machine learning models). Ms. Marchesini stated that ONC is leading efforts to evaluate protective DSIs across several factors, including fairness, validity, appropriateness, effectiveness, and safety. The cornerstone of ONC's proposed rule is trustworthiness, which includes governance and accountability. ONC aims to establish consistency and routine access to specific technical and performance information, such as input features, intended use, output, and ongoing model monitoring. While AI amplifies existing data-related challenges, ONC's current focus is on establishing baseline information visibility and understanding the development and use of AI technology, a crucial step in addressing priorities like public health and health equity.

Dr. Alterovitz stated that VA and other government agencies have contributed valuable datasets suitable for AI IRBs. These datasets are appropriately labeled and accessible via platforms like data.va.gov and data.gov, providing researchers with open and vetted resources to support their work in a responsible and transparent manner.

AI Hallucination

Mr. James asked for clarification of the meaning of "AI hallucination." Mr. Singleton explained that AI hallucination refers to a confident AI-generated response that lacks clear justification based on training data. This concept is analogously termed "hallucination," drawing parallels to the human psychological phenomenon. However, a fundamental distinction lies in the fact that human hallucinations typically involve false perceptions, whereas AI hallucinations manifest as unwarranted responses or beliefs. Mr. Singleton emphasized that the process of discovering hallucinations is crucial, as it fosters learning and improvement in the field. The development of models equipped with hallucination detection mechanisms ensures validation and source verification. Although the existing generation of models may have limitations, ongoing efforts aim to enhance performance and accuracy by mitigating the risk of hallucinations and refining AI capabilities in various applications, including health care diagnosis and legal submissions.

Dr. Alterovitz added that the probabilistic nature of AI models introduces a level of uncertainty to their responses. For example, users can manipulate variables to explore different potential outcomes. Although an answer may not be accurate or relevant, AI models are designed to generate convincing responses regardless of those responses' accuracy. This persuasive capacity stems from the model's training process,

during which it is programmed to generate answers that are shaped by numerous human assessments and comparisons, even if those assessments and comparisons are incorrect. Consequently, users are more likely to be persuaded by conversational AI answers compared to other conventional electronic systems. AI's proficiency in crafting coherent responses is grounded in the models' comprehension of human interactions and communication patterns, both in question-answer scenarios and broader dialogues. However, this tendency can also result in hallucinations, where the model's quest for user satisfaction might overshadow accuracy.

Dr. Hoppe stated that hallucinations should not be regarded as inherently negative. Hallucinations may be undesirable in certain contexts (e.g., providing accurate references for legal cases), but AI hallucinations can also be useful for some applications–such as creative tasks like poetry generation, scriptwriting, and storytelling, where imagination and flair are valued. Thus, the value of AI hallucinations are context dependent. Furthermore, AI, particularly ChatGPT, is not inherently predisposed to excel in all tasks, but rather is designed for specific purposes, such as answering questions.

Data Harmonization

Dr. Hodgkins asked how AI can help harmonize health care standards. Dr. Hoppe stated that AI is helpful with comprehending and analyzing vast volumes of text data and can help with gathering these inputs from the various stakeholders. The application of AI becomes essential in addressing these complexities because AI can harmonize an influx of inputs from the public, including responses to Federal Register Notices (FRNs), which might span diverse focus groups or other influential stakeholders. This process of analysis and summarization of public comments is pivotal in extracting actionable insights and executive elements from the public comment. In essence, AI serves as a tool to streamline and enhance the summarization process, contributing to more effective decision-making by efficiently managing and extracting valuable insights from a multitude of sources.

Health Care Standards Harmonization

Mr. Singleton explained that the challenge in establishing permanent regulations and standards in various fields (e.g., health care standards such as FHIR) is often rooted in the complexity and density of these standards. Such standards can be extensive and challenging to digest, which can hinder their effective implementation and adoption. The ability to summarize and distill these standards into more manageable and understandable formats is crucial. Therefore, by providing concise and comprehensible summaries of complex regulations, individuals and organizations can better grasp the essence and implications of these standards. This process of summarization and simplification allows developers and stakeholders to navigate through various standards more efficiently, facilitating the identification of relevant components and promoting the harmonization of practices across different contexts. Although AI cannot address all challenges, it offers a potential solution by aiding in the cognitive processing and comprehension of intricate regulatory frameworks, thereby enhancing the utilization and alignment of standards.

Mr. Wagner asked whether AI could analyze and compare various existing standards, identifying commonalities and differences to help understand the relationships between different sets of standards, which can aid in the harmonization of standards and the development of a unified health care framework. Ms. Hines added that the challenge of managing multiple standards, particularly in the rapidly evolving landscape of AI and health care, can be complex and potentially hinder effective decision-making. The simultaneous usage of multiple standards in health care transactions (e.g., X12, HL7) has led to NCVHS Committee not making recommendations sought by many stakeholders due to potential impacts of the recommendations sought on health care transactions. Furthermore, the simultaneous usage of both traditional (mature) health care standards and newer emerging ones highlights the need for cohesive and efficient standards management in health care. Dr. Hoppe suggested using data scientists to integrate

and analyze data from various sources. As questions arise and challenges emerge throughout the standards development process, data scientists can provide valuable guidance in structuring, cleaning, and interpreting data to derive meaningful conclusions and ensure that the insights generated by AI contribute to actionable and impactful outcomes. Dr. Alterovitz noted that the process of mapping and aligning different datasets often involves intricate details that may not be easily captured by AI alone. Human expertise and judgment thus become essential for understanding subtle (e.g., contextual) distinctions datasets, making nuanced distinctions, and identifying cases where AI might miss certain connections. This "human-in-the-loop" approach can help refine AI-generated results and ensure the accuracy and relevance of the harmonization process. By combining the strengths of AI with human insights, organizations can achieve more comprehensive and insightful results in tasks such as harmonizing standards, identifying overlaps, and analyzing complex datasets.

AI Regulation and Oversight

Mr. Wagner asked whether there is an existing national U.S. body that regulates AI. Mr. Singleton responded that AI is not currently overseen by a single government organization. Establishing a consolidated AI governing body is challenging due to the diverse nature of AI tools, applications, and domains. AI encompasses a wide range of tools and outcomes, and its use varies significantly across different sectors such as criminal justice and health care. Hence, approaching AI governance requires a tailored and cautious strategy that prioritizes high-value, low-risk opportunities. This strategy involves a step-by-step approach that allows for careful assessment and adaptation as AI technology evolves and matures. The strategy should emphasize incremental progress and ensure that AI complements human decision-making, with the understanding that certain contexts may always require human insight. Dr. Hoppe noted that although there may not be a single consolidated AI governing body, there are valuable resources and frameworks available to guide AI risk management and strategy. One such example is the National Institute of Standards and Technology's (NIST) AI Risk Management Framework (RMF), which provides careful consideration of the AI life cycle and offers insights into effectively mitigating AI-related risks. This framework, although not a governing body itself, offers a comprehensive approach that organizations should adopt to navigate the complexities of AI implementation. Additionally, several federal organizations are actively engaged in addressing AI-related questions and concerns, contributing to the development of national AI strategies and guidelines. The multifaceted nature of AI governance is evident in the involvement of various branches of government, including regulatory bodies, legislative bodies, and even court rulings, as illustrated by the example of ChatGPT's potential to create a patent and its implications for the United States Patent and Trademark Office (USPTO). Therefore, while a centralized governing body may not exist, a collaborative approach involving diverse organizations and entities is essential for establishing effective AI governance principles and practices. Mr. Singleton highlighted that NIST's AI RMF takes a significant approach by focusing on risk assessment at the organizational-mission level rather than solely at the algorithm level, which means that the Framework considers how AI aligns with an organization's overall goals, responsibilities, and context, rather than simply regulating individual algorithms and their specific functionalities.

Dr. Foreman stated that encouraging various industries to consider their own AI oversight and regulations is essential. It is also important to recognize that although creating governance systems may seem challenging, history often shows that significant events prompt the need for regulatory action. Thus, anticipating such possibilities and proactively considering oversight measures can help prepare for the future and ensure responsible AI use.

Ms. Strickland expressed that although AI has immense potential, particularly in government sectors like health care, the challenge lies in ensuring responsible and controlled AI use. Users may not always adhere to guidelines, potentially leading to unintended consequences or misuse of AI technologies. Therefore,

policing and regulating AI is a serious concern. Dr. Hoppe agreed that concerns about the potential harmful impacts of AI are well-founded, especially when it comes to generative AI. Detecting malicious activities can be challenging, particularly when given the lack of clear guidelines to address the misuse of AI-generated content and its impact on society.

AI Impact on Inclusiveness

Dr. Mays raised concerns about the potential negative impacts on minority populations and inclusiveness in AI models. She also expressed concerns about the consequences of AI decisions on individuals' willingness to seek health care or necessary medical attention. Dr. Mays emphasized that the representation of diverse voices in AI model development is essential to ensuring AI trustworthiness and avoiding bias, which is a priority for HHS. Dr. Hoppe highlighted the significance of the NIST AI RMF in detecting concerns about inclusiveness in decision-making processes. He also emphasized that the same inclusiveness principle should be extended to published datasets given their impact on training AI models. The CDC has ongoing development of AI strategies that engage with groups focused on diversity, equity, inclusion, and accessibility. Mr. Singleton noted that existing regulations and frameworks, such as NIST AI RMF and ONC's HTI-1 Proposed Rule, align with HHS's proactive approach to enhance diversity and equity. Additionally, transparency, fairness, and inclusion remain at the forefront of decision-making across all federal agencies that are actively working on other AI frameworks, governance, and regulations.

HHS Office for Civil Rights Update—Melanie Fontes Rainer, JD, Director, and Timothy Noonan, Deputy Director, Office for Civil Rights

In response to concerns over patient privacy following the *Dobbs* decision, OCR held listening sessions with numerous stakeholders including medical providers, advocacy groups, legal representatives, patients, government officials, and national organizations. The aftermath of the *Dobbs* decision resulted in heightened concerns and confusion regarding reproductive health care. Providers nationwide expressed fears of being targeted in other states, even for legal practices, and flagged various scenarios where protected health information (PHI) is being used against doctors and patients. OCR has been receiving feedback from health care entities expressing concerns about the need for stronger regulation to protect reproductive health care privacy.

The current HIPAA Privacy Rule applies to CEs (e.g., health plans, health care clearinghouses, and certain health care providers). The current Privacy Rule allows covered providers and health plans to disclose PHI to "business associates" if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under the Privacy Rule. CEs may disclose protected health information to an entity in its role as a business associate only to help the covered entity carry out its health care functions – not for the business associate's independent use or purposes, except as needed for the proper management and administration of the business associate. The HIPAA Privacy Rule permits regulated entities to use or disclose PHI without an individual's authorization for certain purposes in certain circumstances. These instances encompass situations such as being legally required to disclose PHI, participating in public health endeavors (like sharing data related to COVID-19 fatalities), conducting health oversight activities (such as disclosing PHI to state Medicaid fraud control units), facilitating legal proceedings (for instance, sharing PHI during a court-mandated custody hearing), and serving law enforcement (like revealing PHI pursuant to a search warrant for a criminal Medicaid fraud investigation).

On April 17, 2023, OCR issued an NPRM to solicit comment on its proposal to modify the HIPAA Privacy Rule and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act).

The rule has specific limitations and a defined scope of applicability, as the proposed prohibition is applicable exclusively to *lawful* reproductive health care. The following conditions determine its applicability:

1. Reproductive health care outside the state: the prohibition applies if reproductive health care is sought, obtained, provided, or facilitated outside the state for the purpose of investigation, legal action, or any related proceedings.
2. Reproductive health care within the state: the prohibition is pertinent if the reproductive health care under investigation or legal scrutiny is authorized and deemed lawful within that particular state.
3. Authorization by federal law: the prohibition applies if the reproductive health care is substantiated by federal law, regardless of the state in which such care is provided.

In addition to this rule of applicability, OCR added a rule of construction so that the proposed prohibition does not prevent the use or disclosure of PHI otherwise permitted by the Privacy Rule, unless such use or disclosure is primarily intended for the purpose of investigating or imposing liability on an individual solely for seeking, obtaining, providing, or facilitating reproductive health care. The aim of this construction rule is to prevent the prohibition from interfering with legitimate and authorized activities while targeting instances where reproductive health care is being exploited for investigative or legal actions. For instance, disclosures of PHI remain permissible when used against an individual who knowingly submits a false claim for a reproductive health care payment to the government, which allows for appropriate action against fraudulent activities while safeguarding patient information.

The proposed rule requires a regulated entity obtain a signed attestation, which applies when both of the following conditions are fulfilled: (1) the request is for PHI potentially related to reproductive health care, and (2) the request is health oversight activities, judicial and administrative proceedings, or Law enforcement purposes. Attestation may be electronic, but it may not be combined with any other document.

Discussion

Lawful vs. Unlawful care

Dr. Watzlaf asked for further clarification on the reason for the distinction between lawful and unlawful care in the NPRM. Ms. Fontes Rainer stated that she is unable to divulge extensive information due to the Federal Rulemaking Process but noted that every action currently undertaken is subject to meticulous scrutiny. Therefore, OCR's aim was to propose a legally sustainable rule that could withstand such scrutiny during a period of rapidly changing legal actions.

Proposed Rule Implications

Dr. Watzlaf raised concerns regarding fears of prosecution and litigation among physicians and patients, which can potentially hinder proper medical treatment. Ms. Fontes Rainer cited reports of physicians affiliated with various organizations who are contemplating a shift toward paper-based records, as EHRs like MyChart can inadvertently expose sensitive patient information to potential warrants and subpoenas. For example, if an individual receives lawful medical care in one state but resides in a different state where such care is prohibited, the state that prohibits this care may subpoena medical records from physicians located within that state. This problem extends beyond reproductive health care, as instances of privacy breaches regarding gender-affirming care have also surfaced, particularly concerning gender-affirming care for minors. The proposed Privacy Rule serves as a foundational step for collaborative efforts that are working to address immediate concerns and navigate this recurring challenge.

Dr. Hodgkins stated that requiring attestations will further burden physicians and administrative personnel, and this impact may fall disproportionally on smaller practices that lack personnel with the necessary expertise to effectively manage these attestations. Ms. Fontes Rainer agreed, recognizing the complexity of formulating the proposed rule and careful coordination across various federal agencies.

Ms. Fontes Rainer argued that OCR and other agencies should coordinate to balance implementation of the proposed Privacy Rule to sufficiently uphold statutory law enforcement functions, even these functions are used for pretextual reasons (e.g., claiming to investigate fraud to gain access to records on reproductive health care), while also recognizing that attestations may allow CEs to decline requests if they perceive those requests to be pretextual for investigating reproductive health care. Furthermore, the need for thorough documentation stems from the feedback OCR has been receiving. In certain instances, even with a valid subpoena to a health care organization, law enforcement has entered pharmacies and demanded immediate access to customer records.

Health Data Privacy and Management

Dr. Hodgkins asked whether there are any measures that the federal government can undertake to manage entities that are not covered under the proposed rule (e.g., mobile applications). Ms. Fontes Rainer emphasized that, following the *Dobbs* decision, OCR proactively issued guidance related to applications. Over time, many providers have taken appropriate measures to align with privacy regulations. However, it is imperative to recognize that information on mobile devices, regardless of their source, can carry different implications for personal data security. OCR's regulatory purview is limited, encompassing only a fraction of these entities. To address this gap, OCR diligently disseminated informative materials to the public and collaborated with the Federal Trade Commission (FTC) to encourage best practices. OCR recommends that covered entities establish business associate agreements when sharing information. The OCR website includes a comprehensive guide on this subject. Ms. Fontes Rainer added that discussions with entities like Apple have raised the prospect of establishing front-end regulations to enhance application oversight. Additionally, efforts are being explored to collaborate with medical associations, health care advocacy groups, and privacy organizations to enhance education in this evolving health information landscape.

Ms. Goldstein highlighted the potential release of PHI from disclosures exempted from the attestation requirement, and preventing these disclosures will likely require a more robust regulatory framework. Mr. Noonan stated that although OCR's proposed rule cannot directly address this issue due to OCR's limited authority, exploring potential legislative avenues could pave the way for a more comprehensive approach. Additionally, informing individuals about where their data are stored, how these data are transmitted, and the implications of data disclosures is crucial. Mr. Noonan also mentioned scenarios where reproductive health information is shared with non-HIPAA regulated applications, potentially allowing law enforcement to access that data. Ms. Fontes Rainer added that the emerging trend of information leaks and breaches, particularly in states where gender affirming care is being restricted or banned, is of concerning. For example, individuals within health care facilities have preemptively disclosed sensitive patient data under the guise of whistleblower protections established in state law. Disclosure of sensitive patient data often includes unauthorized posting of patient files, including for minors, on various online platforms. These disclosures illustrate the need for robust security and privacy protocols to ensure controlled access to PHI. Furthermore, educating health care providers on data privacy is imperative, as many may not have anticipated the need to address such scenarios or have trained their staff to effectively handle them.

Ms. Monson asked whether any forthcoming initiatives aim to revise the HIPAA Security Rule or alternatively, to provide comprehensive guidance to protect data from cybersecurity attacks. Ms. Fontes Rainer explained that the health care industry is exponentially experiencing cybersecurity and ransomware

threats. OCR witnessed an alarming surge of nearly 300 percent in instances of ransomware hacking cases. Ms. Fontes Rainer also acknowledged the inherent complexities and constraints that inevitably impact the expeditious execution of strategic responses. Nonetheless, OCR is leading collaborative efforts with the Deputy Secretary to engage key stakeholders in a concerted approach to address this cybersecurity challenge.

Privacy Rule Timeline

Dr. Watzlaf asked, given the considerable volume of feedback, approximately 25,000 comments on the NPRM, what is OCR's timeline for finalizing the proposed Privacy Rule. Ms. Fontes Rainer stated that, despite understaffing challenges, OCR is committed to finalizing the Privacy Rule efficiently and effectively while maintaining a high standard of quality and rigor in its approach. The objective remains to accomplish this undertaking within the upcoming year.

Collaboration Efforts

Ms. Monson asked whether it is feasible for OCR staff to support the NCVHS Subcommittee on Privacy, Confidentiality and Security and explore possible collaboration efforts to work toward shared objectives. Ms. Fontes Rainer and Mr. Noonan expressed their willingness to personally engage in discussions with the NCVHS Subcommittee on Privacy, Confidentiality and Security. Ms. Fontes Rainer noted, however, that OCR's settlement funds have gradually diminished and are anticipated to be fully exhausted by the end of 2024; OCR is actively working with the Deputy Secretary and other relevant stakeholders to develop a comprehensive plan. Thus, OCR's response times might be delayed due to the severe understaffing challenges OCR is experiencing.

Office of Civil Rights Debrief

Dr. Watzlaf stated that it would be beneficial for the Subcommittee on Privacy, Confidentiality and Security to meet regularly with OCR members, given their receptiveness to adopting the changes NCVHS proposes. She added that, considering insights shared by panelists during the meeting, it is also important to thoroughly examine cybersecurity to formulate specific recommendations. The outdated Security Rule highlights the need for a comprehensive update. Ms. Monson noted that allocating time and resources in the upcoming year to thoroughly assess and propose improvements to the Security Rule aligns well with OCR's timeline and focus.

Ms. Goldstein stated that OCR's perspectives shed light on the intricate legal authorities within the administration, both regulatory and legislative, which is a crucial distinction that aids NCVHS in drafting impactful recommendations that can drive meaningful change. OCR's insights are also important in shaping NCVHS's forthcoming report to Congress, offering a clear roadmap for aligning comments on the NPRM and potential future comments on reproductive health issues. Moreover, OCR's comprehensive knowledge of topics, spanning from gender-affirming care to health information exchange and protection across diverse entities, underscores the depth and inclusivity of their discussions. Ms. Goldstein emphasized that OCR's mission resonates with NCVHS's commitment to protecting health information and ensuring equitable access to quality care.

Dr. Mays stated acknowledged OCR's bold approach, citing their robust commitment to gender-affirming care. This boldness indicates the importance of addressing pressing matters straightforwardly, unburdened by hesitation. Thus, aligning NCVHS's approach with OCR's proactive stance could potentially unlock new avenues for progress and transformative health care solutions.

Updates / NCVHS Workplan Development: Subcommittee on Standards—Tammy Banks and Rich Landen, Subcommittee Co-Chairs

NCVHS Role Related to HIPAA Standards

In carrying out its role, NCVHS receives requests for new or updated standards from Standards Development Organizations (SDOs) and new or updated operating rules from Operating Rule Authoring Entities (ORAEs). NCVHS receives input on SDO requests from the Designated Standards Maintenance Organizations (DSMOs) (e.g., HL7, X12). NCVHS then convenes industry and public stakeholders to determine whether the requested updates meet the requirements of HIPAA Administrative Simplification, as amended, for efficiency, effectiveness, and cost/value, as well as inform the development of recommendations to HHS for adoption.

Ms. Banks presented a detailed overview of recent developments within the Subcommittee on Standards. A recommendations letter on updated and new Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) operating rules to support adopted HIPAA Standards was sent to HHS Secretary on June 30, 2023. Additionally, a recommendation letter on the updated version of the X12 Standard for Claims and Electronic Remittance Advice Transactions (Version 008020) was sent to HHS Secretary on June 14, 2023. NCVHS is currently reviewing another X12 request to recommend that the Secretary adopt version 008030 for certain transaction implementation guides:

1. Claim status - 008030X329 Health Care Claim Status Request and Response (276/277).
2. Enrollment - 008030X333 Benefit Enrollment and Maintenance (834).
3. Premium payment - 008030X334 Payroll Deducted and Other Group Premium Payment for Insurance Products (820).

The review process of the Subcommittee on Standards includes (1) overview presentations by X12 to Subcommittee on Standards in July 2023; (2) collaboration with WEDI, named advisor to HHS in the HIPAA statute, to develop and publish a Request for Comment by early September; (3) consultative conversations with partner agencies (e.g., HHS ONC); (4) obtaining input from DSMOs; (5) drafting recommendations; and (6) reviewing draft recommendations with the Executive Subcommittee to present to the Full Committee for discussion, public comment, and vote.

Evolving the Convergence 2.0 Project

The Subcommittee on Standards monitors and makes recommendations to the Full Committee on health data standards by (1) providing outreach, liaison, and consultation with, and serving as a public forum on health information technology standards for the health care industry and federal, state and local governments; (2) making recommendations related to electronic standards and operating rules under HIPAA, privacy and security standards, health terminologies and vocabularies; (3) making recommendations on strategies to promote a continuing process of developing, coordinating, adopting, implementing and maintaining standards; (4) participating in development/publication of the Report to Congress on HIPAA Administrative Simplification; and (5) collaborating with other Federal Advisory Committees on cross-cutting issues as appropriate and when delegated by the Full Committee.

The Subcommittee on Standards is currently reviewing the Convergence 2.0 Project, Modernizing Standards Driven Information Infrastructure across the Healthcare Data Ecosystem (Modernization 1.0), in collaboration with the Privacy and Security Subcommittee. The review process is built upon the Predictability Roadmap, a collaborative effort developed to evaluate barriers to the update, adoption, and implementation of standards and operating rules under the authorities of HIPAA and the Patient

Protection and Affordable Care Act (ACA). The Predictability Roadmap seeks to make industry-driven standards development and integration more concise, simplified, and easily implemented. Notable aspects of this approach encompass regular updates (the shift to smaller but more frequent, "digestible" updates), enhanced pre-adoption testing, and value assessment – including return on investment (ROI), burden, and societal benefits.

The recommendations for improving the HIPAA standards implementation, update, and enforcement process based on the Predictability Roadmap (2017-19) included the following:

1. Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.
2. Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.
3. Improve the visibility and impact of the administrative simplification enforcement program.
4. Provide policy-related guidance from HHS regarding administrative standards adoption and enforcement.
5. Re-evaluate the function and purpose of DSMOs.

These recommendations are derived from 11 original recommendations categorized, seven Calls to Action, and three Measurement Recommendations.

Modernization 1.0 also entails Convergence 1.0 and 2.0, as well as ICAD, which are aimed at harmonizing and integrating standards, with a specific emphasis on the convergence of administrative and clinical data to meet business needs. Convergence 1.0 and 2.0 (2020-22) resulted in the following recommendations:

1. Publish the CMS Interoperability and Prior Authorization proposed rule, which includes the HL7 FHIR standard to support application programming interfaces (APIs) to automate payer and provider prior authorization workflows.
2. Adopt a standard or standards for electronic attachments as soon as possible to meet today's business needs.
3. Evaluate and adopt regulatory flexibility strategies to permit HIPAA Covered Entities to implement new technologies such as FHIR standards and implementation guides (IGs).
4. Streamline the process for adopting HIPAA transaction standards so that this process is reliable, efficient, and timely.

In June 2022, Convergence 1.0 and 2.0 yielded four additional recommendations:

1. Update relevant HIPAA policies to allow the adoption and use of more than one standard per business function.
2. Enable HIPAA Covered Entities to support one or more versions of adopted standards for business functions.
3. Recognizing ONC's existing authority to facilitate the coordination of Social Determinants of Health (SDOH) efforts across HHS components, HHS should expand ONC's authority to include a formalized public process for convening non-federal entities (State, Local, Tribal & Territorial Governments (STLS)) and to align reporting requirements in federal funding opportunities in agencies such as Health Resources & Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and CMS.
4. HHS should develop and publish a guidance framework for Standard Development Organizations and other industry stakeholders that outlines how to develop and report quantifiable estimates for new

and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation, and adoption.

Recommendation 1 centers on developing a systematic approach to evaluate, plan and, if proven, implement multiple standards for HIPAA. Currently, only one HIPAA standard is mandated for a business use (e.g., the X12 278 for Prior Authorization (PA)). In a potential future use scenario, PA is triggered in different locations within the revenue cycle. Triggers for PAs can include patient scheduling, practice management system, electronic medical record. Each of these platforms are built on different standards. The X12 278 may be used in the practice management system, while an FHIR-compliant API could be used when triggered in the electronic medical records (EMR) to perform PA. Payers and their business associates would be required to support both standard implementation guides. Providers and their business associations *could choose* which standard brings the highest business value to their workflows. For instance, a provider chooses to use their practice management system to send a prior authorization that uses an X12 278 transaction with the workflow to a payer. whereas another provider chooses to use a SMART application with their EMR that uses the FHIR-compliant API within the workflow.

Recommendation 2 focuses on allowing HIPAA Covered Entities to support multiple versions of adopted standards to reduce the implementation cost and burden for updates over time. At present, during implementation of a new version of a standard, payers support more than one version of a standard. This allows providers and their business associates to transition to an updated version when they are ready, prior to the mandated implementation date. In a potential future use scenario, if the 008020 claim, professional, dental, and institutional standard, would be mandated, payers would support Versions 005010 and 008020 claim standards. Each provider and their business associate could decide whether there is a business value in moving to the updated version. When an additional updated version is mandated, providers and their business associates would have to move to either Version 008020 or the new version. For instance, dentists would have the option to move to Version 008020 for claims if using this version would provide benefits while those using the professional and institutional claim could remain on Version 005010. This instance would support testing of the business value, ROI, and technical implementation cost by those who find business value.

The Subcommittee on Standards envisions standardized data capture and improved availability of data across the health care data ecosystem that supports individual health care and wellness, health equity/SDOH, public health, health policy, price transparency, coordination of care, improve patient outcomes, burden reduction, privacy and security, and the usability of personal health information. This standardization allows for the betterment of the administrative and clinical information exchange, and ultimately the delivery of healthcare. This result benefits patients, providers, payers, and the system-as-a-whole. At present, the Subcommittee on Standards is discussing potential projects based on past work/listening sessions considerations:

1. Review relevance of HIPAA in the current healthcare ecosystem.
2. Examine mature and emerging standards and how they can co-exist to support current and future business needs and their workflows. In collaboration with HITECH and other appropriate key stakeholders.
3. Evaluate how different industries, countries, SDOs, and others assess standard readiness for national implementation from a business use and technical implementation perspective.
4. Workgroup on Timely and Strategic Action to Inform ICD-11 Policy.

Ms. Banks encouraged Committee members to share their input on these projects with her and Mr. Landon.

Discussion

Dr. Watzlaf asked whether implementing the recommendation that advocates for the adoption and use of multiple standards for business functions will pose cost challenges for payers. Mr. Landen explained that any change to the standard is the result of a request for a new business functionality brought by either a member of the Standards Organization or other stakeholders. The cost consideration is juxtaposed with the need to incorporate necessary functionalities to accommodate the diverse landscape of health care. For example, specific functionalities may not be equally beneficial to dentists, small practices, or surgeons. Thus, the recommendation aims to reduce the burden on health care providers. Ms. Hines noted that a Cigna representative commented online that Cigna has already engaged in discussions regarding the potential need to support multiple standards for HIPAA and is fully prepared to do so. Mr. Ferguson added that HIPAA PAs account for only around 12 to 13 percent of instances. Remarkably, the majority—over 85 percent—of PAs are conducted through alternative means such as phone and fax, resulting in a considerable administrative burden. Therefore, the adoption of more modern and user-friendly technology will significantly enhance compliance rates and increase the nationwide utilization of the standardized HIPAA PA process. Modern technology will also improve efficiency, reduce administrative burdens, and promote consistency in the health care industry, ultimately leading to improved patient care and provider experiences.

Mr. Lenel James asked about the outcome if a newly mandated standard has different or additional required data content (codes) that is not readily available to providers. Mr. Landen explained that there are distinct types of datasets, external and internal X12 codes. External code sets can change independently of the adopted X12 version, thus addressing certain concerns pertaining to code set modifications. On the other hand, internal X12 code sets are tied to the version being employed. Should an entity opt to retain the older X12 version, they consequently remain bound to the existing code set.

Dr. Mays asked what the incentive for individuals to adopt new standards is, despite the increased costs and added work. Ms. Strickland stated that the decision to transition to a new standard version can lead to significant enhancements in efficiency, effectiveness, or other critical operational aspects. For example, the transition to a new standard may offer new networking fields or a new numeration for procedures. Decisions about transitioning to a new version involve a collaborative effort between providers and payors. Although neither party can compel the other to adopt the updated version, each has the opportunity to jointly decide and partner in implementing the change. The determination of which party takes the lead as the decision-maker can vary, depending on factors such as technical capabilities and resources. The decision to transition to new standards holds considerable weight, as it involves comprehensive modifications across the entire process, necessitating regression testing and meticulous adjustments to various aspects of the transaction flow. Currently the adoption process is often met with reluctance from providers to change standards unless compelled by regulatory requirements or mandates. Mr. Ferguson stated that motivations for adopting specific versions are diverse, tailored to the unique benefits that each version offers. A new standard (e.g., new SDOH codes) could facilitate the implementation of disease management programs or contribute to operational cost reduction and streamlined maintenance. For instance, transitioning from a monolithic system to an API-based system has the potential to significantly reduce IT labor expenses by approximately 80 percent. Consequently, the decision-making process necessitates a case-by-case evaluation of the potential advantages and how they align with the goals and needs of trading partners.

Public Comment—Rebecca Hines, Executive Secretary and Designated Federal Officer

Ms. Heather McComas, Director at American Medical Association, asked how health care providers would respond if a health plan required the use of one of the X12 standards or versions in the health plan's

contract. Providers, especially small ones, do not have the negotiating power to overcome this challenge, and therefore, the provider would need to support multiple standards or versions. Ms. Banks explained that, under HIPAA, the provider would have the choice to not include multiple X12 standard versions in their contract with the health plan.

Ms. Donna Campbell, Senior IT Product Manager at Blue Cross Shield and Blue Shield of Illinois, stated that although she appreciates the notion of affording entities the choice to adopt newer versions of X12 standards, she is wary of inadvertently adopting a one-size-fits-all approach. She recalled discussions from the previous NCVHS hearing, indicating doubts about the benefits of migrating 837 transactions to newer iterations. Ms. Campbell added that she personally finds that the enhancements offered by the updated versions hold value, particularly for entities handling substantial 837 claim traffic. In addition, other recommendations await NCVHS consideration, promising substantial value through modern technology tools. Therefore, it is imperative to embrace dual version support, which could fulfill the pressing need for new data, elements, or capabilities in diverse transactions, preventing additional costs incurred via phone communication or alternative technological solutions outside the HIPAA framework. Neglecting this avenue jeopardizes the vision of achieving a convenient and budget-friendly approach for both providers and payers.

NCVHS 2023 Report to Congress—Jacki Monson, Chair

NCVHS is responsible generally for *advising* the Secretary and the Congress on the status of the implementation of Part C of Title XI of the Social Security Act. NCVHS also assists and advises the Secretary in *complying* with the requirements imposed under Part C of Title XI of the Social Security Act. NCVHS additionally studies matters related to the adoption of uniform data standards for patient medical record information and the electronic interchange of such information, and reports to the Secretary recommendations and legislative proposals for such standards and electronic exchange.

The Committee shall submit to Congress a report regarding the implementation of Part C of Title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

1. The extent to which persons required to comply with Part C of the Act are cooperating in implementing the standards adopted under such part;
2. The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards;
3. Whether the federal and state governments are receiving information of sufficient quality to meet their responsibilities under such part;
4. Any problems that exist with respect to implementation of such part;
5. The extent to which timetables under such part are being met.

The 14th Report to Congress (RTC) was completed in 2021 for the reporting period from January 1, 2019 to December 31, 2020. The report featured a comprehensive overview of five significant trends in health information. It provided an insightful evaluation of the progress and status of HIPAA implementation, categorized into two distinct sections: HIPAA Transaction and Medical Code Set Standards, as well as HIPAA Privacy, Security, and Breach Notification. In addition to its assessment of the HIPAA landscape, the report also examined imminent national health information challenges and opportunities that lie ahead. This forward-looking perspective aimed to identify areas of potential growth and innovation within the evolving health care ecosystem.

The NCVHS 2023 RTC presents a comprehensive overview of developments and trends within the health data ecosystem over the two-year reporting period from January 1, 2021, to December 31, 2022. The report elucidates (1) key shifts and changes that have transpired during this period, offering vital context to understand the evolving landscape; (2) notable policy issues impacting the health data eco-system; (3) information and details to address required reporting; and (4) key take-away messages. New members will vote on the RTC during the next NCVHS meeting.

The report outline (executive summary) is as follows:

1. Introduction and Report Overview
2. Evolving Context for Health Information Policy
3. Progress and Status of HIPAA Implementation
    a. HIPAA Transaction and Medical Code Set Standards
    b. HIPAA Privacy, Security, and Breach Notifications
4. Looking Ahead
5. Appendices

NCVHS developed and refined the report outline and identified a writer, Kate Ricker, to lead the drafting process. Ms. Monson is currently reviewing the initial draft and will share it with the Committee. She noted that the report is evolving and will be refined in the upcoming months, and she encouraged Committee members to share their feedback and suggestions. The next step involves focusing on categorization and prioritization, refining the content further, and engaging in substantive discussions during Subcommittee meetings. NCVS aims to have a polished draft by August to September, which allows ample opportunity to refine the content, receive input, and finalize the report. NCVHS tentatively aims to present the report during the Committee meeting scheduled for November 29-30, 2023.

Discussion

Ms. Strickland asked whether the objective is to condense the RTC slightly for the purpose of enhancing its digestibility. Ms. Monson explained that the previous RTC was quite lengthy, and there has not been much enthusiasm expressed by the public or Congress about reading it. To avoid this result, it is crucial to create a more meaningful and impactful report. The executive summary must achieve the challenging goal of capturing the main points without necessitating a full read of the entire document. A compelling and succinct executive summary can make people more likely to read the report's detailed sections if they wish to delve deeper. This approach to the RTC will strike a balance between providing valuable content and avoiding excessive detail, ensuring that the report remains accessible and informative while still being manageable. Ms. Hines added that a significant challenge was initially having an outline with 11 topics in the context setting section. After consulting with long-standing members and seeking input, the outline was narrowed to three or four key topics. However, even with this reduction, a substantial amount of context remains to be provided.

Next Steps and Wrap Up—Full Committee

The next virtual Full Committee meeting is scheduled for November 29-30, 2023.

Closing Remarks and Adjourn—Ms. Monson, Chair

Ms. Monson thanked Subcommittee staff members, invited speakers, and the NICHES team for their support and adjourned the meeting.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

[redacted]

10/26/2023

Chair
National Committee on Vital and Health Statistics

Date